UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
This Document Relates to: UNITED STATES OF AMERICA, *et al.*, *ex rel.* ELISA DICKSON, RELATOR, Plaintiffs, v. BRISTOL-MYERS SQUIBB COMPANY, *et al.*, Defendants.	Case No. 3:13-cv-01039-FLW-TJB **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT** **Motion Day: November 18, 2013**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

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Relator's Third Amended Complaint ("TAC") should be dismissed with prejudice pursuant to Rules 12(b)(1), 12(b)(6), and 9(b) of the Federal Rules of Civil Procedure because it fails to state a claim under the federal False Claims Act ("FCA") or any analogous state statutes.

INTRODUCTION

The FCA is not a general anti-fraud statute that broadly regulates the marketing and sale of pharmaceuticals. The statute applies only when an entity falsely certifies to a government agency that "it has complied with a statute or regulation the compliance with which ***is a condition for Government payment***." *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (emphasis added). The Court should dismiss the TAC because it fails to allege that Defendants made this sort of false statement, as required to state an FCA claim. In particular, dismissal is required here for the following three reasons.

First, the TAC does not cure the deficiencies that caused this Court to dismiss the Medicaid and Medicare Part D allegations of the Second Amended Complaint. Relator's FCA claims are concededly based entirely on "on label" Plavix® prescriptions, and federal law ***requires*** Medicaid and Medicare Part D to reimburse for such on-label prescriptions without inquiry into why particular prescribing doctors chose to write the prescriptions. Neither Medicaid nor Medicare Part D may deny reimbursement based on judgments about whether a doctor's on-label Plavix® prescription was "medically necessary" or "reasonable and necessary." Accordingly, the law required the reimbursements at issue here and there was necessarily no FCA violation.

Relator's conclusory allegations that Pharmacy and Therapeutic ("P&T") committees were "duped" into covering Plavix® does not save her case for the same reason. Relator's speculation that P&T committees might have changed their reimbursement policies if presented with different information does not establish any false certification. Moreover, P&T committees

are required by law to base their coverage decisions on the available science relating to a particular pharmaceutical. Accordingly, Defendants' alleged marketing misrepresentations about Plavix®—even if proven—are legally irrelevant to P&T committee coverage decisions.

Second, after four attempts, Relator still fails to plead the basic elements required to allege fraud under the FCA. Relator's TAC contains general allegations without the critical who, what, where, when, and how of either the alleged false statements or any false claim. As to Relator's new allegations that Defendants deceived each of 50 states' P&T committees to cover Plavix®, there are no facts pled; the TAC consists merely of boilerplate citations to various and sundry statutes and regulations. Even if Relator alleged a viable legal theory of liability, which she has not, the TAC is nonetheless deficient because Relator fails to allege:

- ***who*** made a single false statement to a doctor or a P&T committee;
- ***who*** received or relied on an allegedly false statement from Defendants;
- ***who*** wrote a prescription for Plavix® for its Food and Drug Administration ("FDA")-approved use that was not medically necessary or reasonable and necessary;
- ***what*** false statement was made by anyone at the companies regarding Plavix®;
- ***what*** prescription for an FDA-approved use of Plavix® was not medically necessary or reasonable and necessary;
- ***when*** or ***where*** a single false statement was issued, ***when*** or ***where*** a claim was submitted for Plavix® that was not covered or reimbursable under any program at issue, or ***when*** or ***where*** a prescription of Plavix® for its FDA-approved indication was not medically necessary or reasonable and necessary; or
- ***how*** Defendants' marketing and not doctors' own independent medical judgment caused any medically unnecessary prescriptions for Plavix® to be submitted or had any impact on P&T committee decisions.

Third, the TAC's allegations are based entirely on allegations disclosed in prior federal court litigation, news media reports, or FDA reports. The TAC's regurgitation of these old

allegations is long on conclusions and short on facts, offering only a series of general averments that Defendants over-promoted Plavix® as more effective than other drugs that have already been publicly disclosed.

BACKGROUND

The FDA approved Plavix® (clopidogrel bisulfate) in 1997 for use as monotherapy (*i.e.*, without aspirin) in patients with recent heart attack or stroke or diagnosed peripheral arterial disease ("PAD"). The FDA's approval was based on the results of the CAPRIE clinical trial, which demonstrated an 8.7% relative risk reduction benefit from using Plavix® compared to aspirin across the entire study.[1] After further studies, FDA approved Plavix® for dual therapy with aspirin for the treatment of patients with acute coronary syndrome ("ACS"), a set of clinical signs and symptoms occurring when the heart muscle does not get enough blood due to plaque narrowing or blocking the arteries leading to the heart. *See* TAC, Ex. B (Plavix® Package Insert), at 2. Physicians widely prescribe Plavix® to reduce the risk of blood clots, which can cause heart attacks or strokes.

After the Federal and state government co-plaintiffs declined to intervene, *see* Declination (Doc. 25), Relator filed her Second Amended Complaint ("SAC"). Defendants moved to dismiss the SAC and that motion was granted in part by the United States District Court for the Southern District of Illinois (the "transferor court") and in further part by this Court after the case was transferred to the MDL. The Court granted Relator leave to amend her complaint and she filed the TAC on September 20, 2013. *See* Third Am. Compl. (Doc. 90).

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[1] *See* TAC, Ex. B, at 24; TAC, Ex. F (CAPRIE Trial Abstract). *See also* CAPRIE Steering Committee, *A randomized, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE)*, 348 Lancet 1329 (1996) (attached to Certification of M. Watson ("M.W. Cert.") as Ex. A).

ARGUMENT

I. THE TAC FAILS TO STATE A CLAIM UNDER THE FALSE CLAIMS ACT

A. False Marketing Allegations Do Not State a Claim Because Compliance With Marketing Regulations is Not a Prerequisite to Payment

Relator's allegation that Defendants' Plavix® marketing "caused physicians and pharmacists to either expressly or impliedly make false certifications about Plavix®'s efficacy or necessity for the patient's treatment," TAC ¶ 210, is insufficient to state a claim. Relator concedes that the Plavix® prescriptions at issue here were for indications approved by FDA. As a result, Medicaid and Medicare Part D were required to reimburse on-label Plavix® prescriptions, regardless of how the drug was marketed or why particular doctors wrote prescriptions for the on-label use. Under these circumstances, there can be no FCA liability.

Wilkins is directly on point. In *Wilkins*, the Relator claimed that defendant's improper marketing practices, such as use of unapproved marketing materials, led to false Medicare claims. But the Third Circuit explained that a false certification claim arises only when defendants cause a physician or pharmacist to "knowingly falsely certif[y] that [they] ha[ve] complied with a statute or regulation the compliance with which ***is a condition for Government payment***." *Wilkins*, 659 F.3d at 295, 305 (emphasis added). The Court thus affirmed dismissal, stating that "allegations that appellees violated the [marketing] regulations do not state a plausible claim for relief under the FCA inasmuch as the Government's payments of appellees Medicare claims were not conditioned on their compliance with the marketing regulations." *Id.* at 308. *See also United States ex rel. Simpson v. Bayer Corp.,* Civ. Action No. 05-3895 JLL, 2013 WL 4710587, at *9 (D.N.J. Aug. 30, 2013) (dismissing misbranding and off-label marketing allegations because relator "does not point to any [marketing] regulations which would demonstrate that compliance is a condition of payment"); *United States ex rel. Ge v.*

Takeda Pharm. Co., Civ. Action No. 10-11043-FDS, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) ("Because relator has not adequately established that compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6).").

B. Relator's "Medically Necessary" and "Reasonably Necessary" Allegations Fail to State a Claim Because the Federal Healthcare Programs Are Required to Reimburse On-Label Prescriptions

In an attempt to conjure up a "certification" that could give rise to FCA liability, Relator asserts in conclusory fashion that doctors submitted claims for Plavix® for FDA-approved indications that were not "medically necessary" or "reasonable and necessary." But Medicaid and Medicare Part D were ***not*** permitted to deny reimbursement of a covered product because they deemed a given prescription to not be "medically necessary" or "reasonable and necessary." To the contrary, those programs were ***required*** to reimburse on-label Plavix® prescriptions unless a plan followed one of the statutorily permitted means for restricting coverage, and Relator does not allege that any plan did follow these specific statutory procedures restricting coverage.

1. Relator Admits That Medicaid and Medicare Part D Programs Covered Plavix® for Its On-Label Uses at All Times

Relator admits that Plavix® was covered for FDA-approved indications by the health care programs at issue in this case. *See* TAC ¶¶ 133-183; 190. Courts have repeatedly dismissed FCA claims for prescriptions reimbursed by the programs at issue —without regard to whether individual prescriptions were medically reasonable or necessary. *See United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 285-86 (D. Mass. 2012) *reconsideration denied*, Civ. Action No. 07-12153-RWZ, 2012 WL 3929822 (D. Mass. Sept. 7, 2012) (holding that claims are not "false or fraudulent" where the Medicaid program reimburses for the alleged

use of the product and dismissing claims where relator failed to allege that any state Medicaid programs elected not to cover the alleged off-label indication); *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, No. 1:09-cv-1086 AJT, 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011) (dismissing FCA claims for failure to allege that the prescriptions were "not reimbursable under the specific, governing programs and regulations"); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) (noting that "state approval [of coverage for a drug] undermines the assertion of a 'false claim'" and stating that "if a state knowingly chose to reimburse for a drug, even for an off-label use, after a prior authorization review, liability would not attach because extensive government knowledge would 'negate the intent requirement under the FCA as a matter of law.'") (quoting *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000)). Defendants are aware of no authority which has imposed FCA liability where a drug has been prescribed for an FDA-approved indication and reimbursed under Medicaid or Medicare Part D, in the absence of kickbacks, which has not been alleged here.

In a recent case from this district, for example, Judge Linares dismissed FCA claims alleging that Bayer engaged in off-label promotion in violation of the Federal Food Drug and Cosmetic Act ("FDCA") for its drug Trasylol, a physician administered drug reimbursed under Medicare Part B. *See Simpson*, 2013 WL 4710587, at *10. Relator alleged that the defendant downplayed the risks of Trasylol in its marketing and promoted the drug for uses for which the FDA had not approved the drug as safe and effective in violation of the FDCA. *Id.* at *1. The court dismissed the relator's claims that the defendants' marketing caused the drug to be prescribed in instances that were not "reasonable and necessary," holding that the drug "was approved by the FDA at all times" and that relator did not argue that "[d]efendant caused claims to be submitted that were not ***reimbursable***." *Id.* at *10. (emphasis added). The same is true

here: Relator admits Plavix® was approved by the FDA at all times and that all programs at issue covered Plavix® for its FDA-approved indications.

United States ex rel. Polansky v. Pfizer, 914 F. Supp. 2d 259 (E.D.N.Y. 2012), is also instructive. There, relator alleged that Pfizer engaged in an "illegal marketing campaign for Lipitor" that violated the FCA by marketing Lipitor for its FDA-approved use (to lower cholesterol) to patient populations with risk factors and cholesterol levels that did not warrant drug intervention according to the National Cholesterol Education Program Guidelines, which were referenced in the drug's label. *Id.* at 260. The court dismissed the FCA claims because Pfizer was not "doing anything 'false' or [] aiding in the submission of 'false claims' when it markets the drug as effective to patients who fall outside of the Guideline parameters . . . [because] [i]t is marketing the drug, after all, for an FDA sanctioned purpose - to lower cholesterol." *Id.* at 265; *see also id.* at 263 ("[A]s long as Pfizer markets the drug to lower cholesterol, it is doing what the label permits."). Likewise here, Relator's allegations concerning promotion for FDA-approved indications fail to state a claim.

2. Medicaid Does Not Impose a Separate "Medically Necessary" Precondition for Payment for On-Label Prescriptions

Relator's Medicaid claims fail because there is no separate "medically necessary" condition of Medicaid reimbursement for on-label Plavix® prescriptions. Medicaid ***mandates*** reimbursement of covered outpatient drugs such as Plavix® when prescribed for a "medically accepted indication,"[2] including any on-label use, subject to four statutorily provided exceptions. *See* 42 U.S.C. § 1396r–8(d) (listing the only permissible restrictions of coverage); *Pharm. ¶ &*

[2] A "medically accepted indication" means "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." *See* 42 U.S.C. § 1396r-8(k)(6).

Mfrs. of Am. v. Walsh, 538 U.S. 644, 652 (2003) ("[T]he law requires the State to provide coverage . . . unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act."); *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1336 (S.D. Fla. 2006) (state Medicaid program may not "deny reimbursement for a covered outpatient drug" prescribed for a medically accepted indication because doing so is "not permitted by the Medicaid Act"). Yet Relator has not alleged that a single state has invoked any of those exceptions to limit reimbursement for on-label Plavix® prescriptions. *See* TAC ¶¶ 133-183. Indeed, as discussed above, Relator admits that Plavix was covered by every State Medicaid program at issue at all times ***without restriction***. *Id.*

Relator cites a federal regulation and a hodgepodge of state provisions that Relator purports establish a "medically necessary" requirement for coverage of prescription drugs prescribed for on-label uses. TAC ¶¶ 51-102. These authorities do no such thing. The federal regulation permits states to restrict the "amount, duration, and scope" of coverage, such as the number of refills permitted—but not to deny coverage for an on-label use. *See* 42 C.F.R. § 440.230 (entitled "Sufficiency of amount, duration, and scope").[3] And the state authorities Relator cites merely allow limitations consistent with federal law[4] —none override the federal

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[3] *See* 60 Fed. Reg. 48442-01 ("[42 U.S.C. § 1396r-8] curtails a State's authority to exclude drugs from coverage . . . [but] did not alter the State's authority to establish amount, duration, and scope restrictions [provided under 42 C.F.R. § 440.230], and, in fact, specifically recognized States' authority to impose additional restrictions on the quantities per prescription and the number of refills.").

[4] The state programs cited by Relator must comport with federal law including the Medicaid Rebate Act and the coverage requirements of 42 U.S.C. § 1396r–8(d). *See, e.g.*, Ind. Code Ann. § 12-15-13-2(b) ("If federal law or regulations specify reimbursement criteria, payment shall be made in compliance with those criteria."); ME ADC 10-144 Ch. 101, Ch. I, § 1.20 ("Because MaineCare is subject to Federal statutes in order to receive Federal funding, compliance with Federal regulations and/or law is necessary, and requires that such laws will supersede any State regulation that may be contradictory."); 130 Mass. Code Regs. 406.413(C)(4) (setting forth drug

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statute requiring reimbursement of on-label prescriptions of FDA-approved drugs. Moreover, Relator does not identify even a single Plavix® prescription that was written in violation of any restriction imposed pursuant to § 440.230 or the state authorities Relator cites.

Instead, Relator seeks to superimpose a "medically necessary" precondition to payment on all covered Medicaid prescriptions outside of the mechanisms permitted by the Medicaid statute and in contravention of the federal Medicaid Rebate Act. In *Edmonds*, the court held that doing so would violate federal law. 417 F. Supp. 2d at 1330-31 ("The statutory scheme is carefully constructed in such a way to precisely circumscribe the only methods by which a state may remove a Medicaid-eligible drug from coverage."). The court held that by adding a restriction outside of the four exceptions permitted in the federal Medicaid Act, Florida Medicaid "arbitrarily determined that a double-blind . . . randomized clinical trial is the standard it will apply [to coverage of off-label uses], disregarding the fact that the Act directs coverage when a use is supported by citation in a compendia, a different standard." *Id.* at 1338. The Court recognized the danger of allowing individual states to impose their own restrictions: "[F]ifty states could establish their own criteria for denying coverage of a Medicaid-eligible drug without going through the formulary process or employing the other methods delineated in the statute for excluding a drug," and this would, "contravene[] provisions of the Medicaid Act and Congress'

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coverage limitations that mirror those permitted under 42 U.S.C. § 1396r–8(d)(1) and stating Medicaid "does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert"); S.C. Code Ann. Regs. 126-399 ("When the requirements of the State and the Federal regulations are not in agreement, the requirements of the Federal regulations shall prevail."); *see also* Alaska Stat. Ann. § 47.07.030; Ill. Dep't of Healthcare and Family Servs., Handbook for Providers of Med. Servs. at 15, § 104 (2009), http://www.hfs.illinois.gov/assets/100.pdf; Kan. Admin Regs. § 30-5-92(h); 907 Ky. Admin. Regs. 3:130; La. Admin. Code tit. 50, pt. XXIX, § 107; Mont. Code Ann. § 53-6-101(1); N.M. Stat. Ann. § 27-2-12(A); N.D. Admin. Code 75-02-02-02; 55 Pa. Code § 1101.11; 12-7 Vt. Code R. § 5.

intent to establish uniformity in Medicaid drug coverage." *Id.*

3. Medicare Part D Does Not Have a "Reasonable and Necessary" Precondition of Payment for On-Label Prescriptions

Nor is there any "reasonable and necessary" precondition of payment for Medicare Part D reimbursements of on-label prescriptions that are covered by a Medicare Part D plan. Part D prescription drug plans ***may*** exclude from coverage drugs that are not "reasonable and necessary." 42 U.S.C. § 1395w-102(e)(3)(A). But Relator does not allege that any such Medicare Part D plan ***did*** restrict coverage of Plavix®. Instead, Relator states generally that "Medicare Part D plan sponsors have utilized this statute [*i.e.*, 42 U.S.C. § 1395w-102(e)(3)(A)] to limit reimbursement of prescription drugs." TAC ¶ 45 (citing four plans—CIGNA, L.A. Care, Inland Empire, and TEAMStar). Relator does not allege that any of these plans did not reimburse for Plavix®, nor could she, as each of these plans covered Plavix® without restriction. The Plavix® prescriptions at issue here were therefore necessarily reimbursable and cannot constitute false claims.[5]

Another flaw in Relator's theory of liability is that even if a "reasonable and necessary" standard did apply, prescriptions of Plavix® for its FDA-approved indications would satisfy that standard. For example, the "reasonable and necessary" standard, when used as a statutorily-imposed condition of payment in Medicare Part B, includes drugs when they are prescribed for "medically accepted" or FDA-approved indications. *See Simpson*, 2013 WL 4710587, at *11 ("Courts and government reimbursement programs generally consider off-label uses to be medically accepted and thus 'reasonable and necessary' if they are supported by a listing in a

[5] Relator asserts claims regarding CHAMPUS/TRICARE, CHAMPVA, the Federal Health Benefit Program, and other federal health care programs, but fails entirely to allege any preconditions of payment under those programs that were violated or for which certifications of compliance were submitted. Those claims should be summarily dismissed.

major drug compendium"); *see also* Medicare Benefits Policy Manual, Chapter 15, 50.4.1, *available at* http://www.cms.gov/Regulations-and-Guidance/ Guidance/Manuals/downloads/ bp102c15.pdf ("[d]rugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of [the 'reasonable and necessary'] requirement when used for indications specified on the labeling.").[6]

4. Relator's Formulary Allegations Fail to Save Her Claims

Relator tries to sidestep the lack of any false certification of compliance with a condition of payment by alleging on "information and belief" that Medicaid and Medicare Part D formularies would have excluded coverage of Plavix® but for Defendants' allegedly "false marketing," *see* TAC ¶¶ 133-183; 190. But those speculative allegations do not render claims for Plavix® false and do not avoid dismissal. At all times, Plavix® ***was*** covered by the programs at issue. *See* Section I.B.1.

As a result, whatever reimbursement rules or policies Relator argues those programs ***should have*** adopted in the absence of claimed misrepresentations, the point remains that Relator has not and cannot identify any false certification which ***actually was*** a prerequisite to payment here.[7] *See Wilkins*, 659 F.3d at 305; *see also United States v. Infomedics, Inc.*, 847 F. Supp. 2d

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[6] *See also* Medicare Benefits Policy Manual, Chapter 15, at 50.4.2 (where a drug is not prescribed for its FDA approved indication, the drug may nevertheless "be covered under Medicare [Part B] if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice"); *United States ex rel. Strom v. Scois Inc.*, 676 F. Supp. 2d 884, 886 (N.D. Cal. 2009) (stating the "'medically accepted' terminology clarifies the applicable statutory language, which provides coverage for uses that are 'reasonable and necessary'" and holding that Relator had adequately pled an FCA violation for submission of claims for off-label uses of the drug under Medicare Part B because those uses were not medically accepted).

[7] Moreover, even if a Medicaid P&T committee removed Plavix from formulary, the state Medicaid program would be required to cover the drug subject to a prior authorization requirement. *See* 42 U.S.C.A. § 1396r-8(d)(4)(D) (requiring state Medicaid plan to permit

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256, 265 (D. Mass. 2012) (dismissing allegations that submission of adverse event reports ***would have*** caused FDA to order warnings on the product that would have reduced reimbursement claims) (emphasis added); *Ge*, 2012 WL 5398564, at *6 (dismissing claims that FDA ***would have*** taken a drug off the market if defendant had reported adverse events because the "FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements") (emphasis added).

In any event, Relator's assertions about hypothetical decisions by Medicaid or Medicare Part D P&T committees fail to state a claim because they are wholly speculative. *See United States ex rel. Feldstein v. Organon, Inc.*, No. 07-2690, 2009 WL 961267, at *11 (D.N.J. Apr. 7, 2009) (dismissing "highly speculative" allegations lacking "concrete evidence" to support them). Indeed, Relator fails to allege how any of Defendants' allegedly false promotional statements could have been material to decisions by P&T committees because, by law, those committees were required to evaluate independently the clinical data and information that Relator claims was mischaracterized. For a covered outpatient drug like Plavix® prescribed for an on-label use, Medicaid P&T committees must make a ***clinical*** determination of whether to exclude Plavix® from its formulary based on the drug's labeling. *See* 42 U.S.C. § 1396r-8(d)(4)(C) ("A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of ***safety, effectiveness, or clinical outcome*** of such treatment for such population over other drugs included in the formulary . . . ") (emphasis added). Thus, Relator fails to allege how the alleged

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"coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program") The TAC contains no allegation that any state prior authorization program applied a "medically necessary" standard as part of its prior authorization program.

false *marketing statements* would have any bearing on P&T committee decisions, which must be based on clinical information regarding safety, effectiveness or outcomes from the product's labeling.[8]

II. RELATOR'S COMPLAINT SUFFERS FROM FATAL PLEADING DEFICIENCIES

Relator's TAC also suffers from fatal pleading deficiencies that should mandate dismissal pursuant to Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure.

First, Relator fails to allege fraudulent statements with the requisite specificity and her complaint should be dismissed accordingly. *See e.g., Hall v. Bristol-Myers Squibb Co.*, Civ. Action No. 06-5203(FLW), 2009 WL 5206144 (D.N.J. Dec. 30, 2009); *Mattson v. Bristol-Myers Squibb Co.*, Civ. Action No. 07–908 (FLW), 2009 WL 5216966 (D.N.J. Dec. 30, 2009).

In *Hall* and *Mattson*, both personal injury cases involving state law fraud-based claims regarding Defendants' marketing of Plavix®, this Court evaluated the sufficiency of the allegations and concluded that plaintiffs failed to meet the requirements of Rule 9(b) because none had alleged "the connection between Defendants' conduct and Plaintiff's resultant injury . . . [including] any specific advertisements she viewed, how she was misled by these advertisements, how these advertisements affected her prescription for Plavix and how these advertisements caused any of her injuries." *Mattson*, 2009 WL 5216966, at *9; *Hall*, 2009 WL 5206144, at *9. Moreover, in each case, this Court found insufficient complaints that failed to allege plaintiffs' "physicians personally received a misrepresentation of fact from Defendants

[8] Even where states may consider the cost of drugs in making formulary decisions, and Relator has not alleged anywhere in the TAC a basis for those committees to do so or the requirements that would need to be met under 42 U.S.C. § 1396r-8(d)(4)(E) or any other provision, P&T committees still must make a clinical determination in accordance with federal statutory requirements and Relator does not allege that any cost information was withheld or misrepresented by Defendants.

and relied upon that misrepresentation in deciding to prescribe Plavix to Plaintiff" and failed to identify "the [sales] representatives [that allegedly made false statements], what was said, when it was said, to whom it was said—whether it was communicated to Plaintiff's physician—and how these statements relate to Plaintiff's prescription of Plavix." *Mattson*, 2009 WL 5216966, at *10; *Hall*, 2009 WL 5206144, at *10.

Similarly, here, Relator fails to identify: (i) a single physician to whom a misrepresentation was made; (ii) a single instance (date, time, and location) in which she or any other sales representative made an alleged misrepresentation; (iii) a single physician that prescribed Plavix® as a result of such a misrepresentation; or (iv) any Medicaid or Medicare beneficiary that received and filled such a prescription. Relator's failure to allege the speaker of a single misstatement or the recipient of a false statement is fatal to her claims. *See Mattson*, 2009 WL 5216966, at *9-10; *Hall*, 2009 WL 5206144, at *9-10; *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004) (plaintiff must allege "who made a misrepresentation to whom and the general content of the misrepresentation"); *Klein v. Gen. Nutrition Co. Inc.*, 186 F.3d 338, 345 (3d Cir. 1999) (to meet 9(b), "plaintiff [must] identify the speaker of the allegedly fraudulent statements").

Second, Relator fails to provide a single well pleaded factual allegation that even one doctor submitted a prescription for an FDA-approved indication for Plavix that was not necessary for a patient. *See* TAC ¶ 195-96. Relator thus fails to allege even one false claim, the "*sine qua non*" of an FCA violation. *United States ex rel. Budike v. PECO Energy*, 897 F. Supp. 2d 300, 319 (E.D. Pa. 2012); *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D.113, 124 (W.D. Pa. 2006); *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, Civ. Action No. 05-2927 KSH, 2010 WL 5466043, at *7-9 (D.N.J. Dec. 30, 2010) (dismissing on 9(b) grounds

where plaintiff failed to identify a single false claim submitted to the government); *United States ex rel. Schmidt v. Zimmer, Inc.*, No. Civ. A. 00–1044, 2005 WL 1806502, at *3 (E.D. Pa. July 29, 2005) ("Because [relator] has failed to identify with particularity a specific false claim, there is no nexus between the allegedly illegal marketing scheme and the FCA.").

In *United States ex rel. Lampkin v. Johnson & Johnson, Inc.*, Civ. Action No. 08-05362 JAP, 2013 WL 2404238 (D.N.J. May 31, 2013) (Pisano, J.), for example, this court dismissed an FCA case alleging that defendants engaged in off-label promotion and provided kickbacks to doctors because the relator failed to allege "a single doctor that prescribed [the product] for an off-label use" or a doctor "who submitted a claim for reimbursement to the government" but rather alleged that claims for reimbursement were submitted to the government based on off-label prescriptions without factual support. *Id.* at *4. *See also Bartlett*, 234 F.R.D. at 122 (holding plaintiff's failure to "produce even one specific claim by the Defendants" was fatal). Likewise, here, Relator fails to identify a single doctor that prescribed Plavix® in a manner that was not medically necessary—a standard Defendants maintain does not apply here—that was in turn submitted for reimbursement to a federal healthcare program.

Third, Relator's formulary allegations are entirely deficient. No less than 109 of the 456 paragraphs in the TAC are based on "information and belief" assertions that P&T committees, states, and insurance companies would have excluded Plavix® from coverage had Defendants not engaged in the alleged false marketing. Where allegations are based on information and belief, the complaint must set forth a specific factual basis for such belief. *Zimmer*, 2005 WL 1806502, at *3 n.6 ("[I]nformation and belief allegations remain subject to the particularity requirements of Rule 9(b), and [plaintiff] must set forth the facts on which his belief is founded."); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)

("boilerplate and conclusory allegations will not suffice."); *Zavala v. Wal-Mart Stores, Inc.,* 393 F. Supp. 2d 295, 313 (D.N.J. 2005) ("[I]t is well settled that Rule 9(b) applies even when the fraud relates to matters within the knowledge of the defendant and that allegations based on information and belief do not satisfy Rule 9(b) unless the complaint sets forth the facts upon which the belief is founded"). No such factual basis is specified here.

Further, Relator fails to allege even on information or belief: (i) **who** from the companies met with or communicated with any P&T committees or **who** on any P&T committees received such information; (ii) **when** and **where** any such meetings or communications took place; (iii) **what** misleading materials and statements were presented to the P&T committees; or (iv) **how** any such statements duped P&T members into including Plavix® on their formularies.

Fourth, Relator fails to provide particularized allegations to support a finding that Defendants' conduct ***caused*** doctors to submit medically unnecessary claims (provided that standard applies) or caused P&T committees wrongly to include Plavix® on formularies. *See, e.g.*, *City of Phila. v. Beretta U.S.A. Corp.*, 277 F.3d 415, 423 (3d Cir. 2002) (affirming dismissal of complaint that failed adequately to allege causation); *United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977) ("[A] causal connection must be shown between loss and fraudulent conduct and that a broad 'but for' test is not in compliance with the [FCA]."). In fact, Relator provides no factual basis to suggest that marketing, as opposed to the independent medical judgment of physicians caused any particular prescription to be written. *See Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1355-56 (3d Cir. 1992); *Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556, 562-63 (D.N.J. 2013) ("Indeed, a patient's doctor, who stands between the patient and the manufacturer, is in the best position to professionally evaluate the patient's needs, assess the risks and benefits of available drugs, prescribe one, and supervise its use."); *Heindel v. Pfizer, Inc.*,

381 F. Supp. 2d 364, 382 (D.N.J. 2004) ("It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.") (citation omitted); *Polansky*, 2009 WL 1456582, at *7 ("[P]hysicians who wrote prescriptions were not unsophisticated lay persons. Consequently, it is reasonable to assume that they were familiar with the [relevant standards of practice]"); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, Civ. Action No. 06-3044(FLW), 2008 WL 5413105, at *9 (D.N.J. Dec. 23, 2008) (questioning whether "independent and individualized decision-making of physicians prescribing [the subject drug] breaks any chain of causation between Defendants' alleged misconduct and Plaintiffs' payment for the medication."). Likewise, P&T committees are independent and make informed decisions about what drugs to reimburse and Relator has provided no factual basis to conclude that the Defendants' allegedly false marketing was a "substantial factor" in any formulary decisions.[9]

III. THE COMPLAINT SHOULD BE DISMISSED FOR LACK OF JURISDICTION PURSUANT TO THE PUBLIC DISCLOSURE BAR

Relator's claims are prohibited by the public disclosure bar to the FCA, which "exclude[s] *qui tam* actions based upon allegations of fraud or fraudulent transactions that have been publicly disclosed prior to their filing." *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332 (3d Cir. 2005). Because Relator's TAC merely re-hashes prior publicly disclosed

[9] *See*, *e.g.*, *In re Neurontin Mktg., Sales Practices and Prods. Liab. Litig.*, 257 F.R.D. 315, 332 (D. Mass. 2009) ("P & T Committees are usually comprised of independent physicians from various medical specialties [who] review a variety of types of information in evaluating a drug, including the FDA-approved label, clinical trials, randomized control studies, uncontrolled studies, other clinical literature, and . . . experience with how patients respond to a drug in the real world.") (internal quotations and citations omitted).

allegations, the Court lacks subject matter jurisdiction and must dismiss the suit. *See* 31 U.S.C. §3730(e)(4); *United States ex rel. Atkinson v. PA Shipbuilding Co.,* 473 F.3d 506, 523 (3d Cir. 2007).

The public disclosure bar applies here because (1) there has been a "public disclosure"; (2) "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media"; (3) of allegations or transactions; (4) Relator's *qui tam* action is "based upon" such publicly disclosed allegations; and (5) Relator is not the "original source" of the information. *Paranich*, 396 F.3d at 332 (citation omitted). Relator's suit is barred under the FCA because it is based on publicly disclosed information, and she cannot demonstrate that she is the "original source" of the information.

A. Relator's Allegations Are Based Upon Public Disclosures

"To be based on allegations or transactions of fraud, claims need not be 'actually derived from' public disclosures. . . . Rather, claims need only be 'supported by' or 'substantially similar to' public disclosures." *United States ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 237 (3d Cir.2013). Here, allegations "supported by" and "substantially similar" to Relator's allegations were previously disclosed in news media, federal government reports, or federal product liability suits filed in this District ("N.J. Suits").[10] Exactly like the TAC, the N.J. Suits

[10] *See, e.g., Hall v. Bristol-Myers Squibb Co.*, No. 06-5203 (D.N.J.); *Adkins v. Bristol-Myers Squibb Co.*, No. 07-901 (D.N.J.); *Barge v. Bristol-Myers Squibb Co.*, No. 07-783 (D.N.J.); *Booth v. Bristol-Myers Squibb Co.*, No. 07-1180 (D.N.J.); *Bunting v. Bristol-Myers Squibb Co.*, No. 06-6052 (D.N.J.); *Goldenbogen v. Bristol-Myers Squibb Co.*, No. 07-1188 (D.N.J.); *Gonzalez v. Bristol-Myers Squibb Co.*, No. 07-902 (D.N.J.); *Mayberry v. Bristol-Myers Squibb Co.*, No. 07-942 (D.N.J.); *Money v. Bristol-Myers Squibb Co.*, No. 07-1100 (D.N.J.); *Moscinski v. Bristol-Myers Squibb Co.*, No. 06-6055 (D.N.J.); *Naber v. Bristol-Myers Squibb Co.*, No. 06-6269 (D.N.J.); *Robinson v. Bristol-Myers Squibb Co.*, No. 07-267 (D.N.J.); *Rutledge v. Bristol-Myers Squibb Co.*, No. 07-1099 (D.N.J.); *Smith v. Bristol-Myers Squibb Co.*, No. 06-6053 (D.N.J.);

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and media disclosed the allegations that Defendants promoted Plavix® as superior to aspirin,[11] including by allegedly misrepresenting data from the CAPRIE study.[12]

The *Hall* Complaint, contains similar allegations to the allegations in the TAC, *see* TAC ¶¶ 8-12, regarding the promotion of Plavix® as superior to aspirin, including misrepresenting CAPRIE:

> The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies [including CAPRIE], should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. . . . Still, BMS and Sanofi continued to exaggerate the results of their own studies and to make false statements in their advertising and promotional materials for the purpose of increasing their profit from Plavix sales. Ex. B ¶¶ 14-15.
>
> [T]he Defendants promotional material misled consumers about their own study, called CAPRIE . . . [when] the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin. Ex. B ¶ 21.

Those same allegations were also publicly disclosed in federal reports – untitled letters from the FDA – containing allegations of unsubstantiated promotional claims that are identical to the allegations pled in the TAC and the N.J. Suits. *See Atkinson,* 473 F.3d at 525-26 (allegations

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Street v. Bristol-Myers Squibb Co., No. 07-1182 (D.N.J.); *Begley v. Bristol-Myers Squibb Co.*, No. 06-6051 (D.N.J.); *Davis v. Bristol-Myers Squibb Co.*, No. 07-1098 (D.N.J.); *Cooper v. Bristol-Myers Squibb Co.*, No. 07-885 (D.N.J.); *LeBarre v. Bristol-Myers Squibb Co.*, No. 06-6050 (D.N.J.); *Newell v. Bristol-Myers Squibb Co.*, No. 07-1184 (D.N.J.); *Solomon v. Bristol-Myers Squibb Co.*, No. 07-1102 (D.N.J.); *Dawkins v. Bristol-Myers Squibb Co.*, No. 07-1186 (D.N.J.); *Mattson v. Bristol-Myers Squibb Co.*, No. 07-908 (D.N.J.); *Crowe v. Bristol-Myers Squibb Co.*, No. 11-6551 (D.N.J.); *Guss v. Bristol-Myers Squibb Co.*, No. 11-6550 (D.N.J.).

[11] *Compare*, *e.g.*, Second Am. Compl. ¶¶ 23-24, *Hall v. Bristol-Myers Squibb Co.*, No. 06-5203 (D.N.J. May 1, 2009) (M.W. Cert. Ex. B), *with* TAC ¶ 195. *See also* Kelly Holleran, *Plavix makers sued in St. Clair County*, Madison-St. Clair Record, Nov. 4, 2010, *available at* http://madisonrecord.com/issues/895-product-liability/231003-plavix-makers-sued-in-st-clair-county (M.W. Cert. Ex. C).

[12] *Compare, e.g.*, M.W. Cert. Ex. B ¶¶ 14-15, 21-24, 29, *with* TAC ¶¶ 3, 8-12; 115-118. *See also* Comparison Chart of Allegations Regarding Promotion (M.W. Cert. Ex. D).

in a letter provided by the government, government investigation reports, and disclosures following FOIA requests are public disclosures). The May 2001 untitled letter containing those allegations[13] is quoted in both the TAC, *see* TAC ¶ 8, and the *Hall* Complaint, ¶ 21.

Relator's allegations that Defendants downplayed the risk of gastrointestinal bleeding in Plavix® patients by failing to disclose a study published on January 20, 2005 in the New England Journal of Medicine (the "Chan Study") are also substantially similar to allegations in the N.J. Suits[14] and media reports[15] and thus are based on public disclosures. The *Hall* Complaint contains similar allegations to paragraph 123 of the TAC regarding the Chan study:

> Defendants' nearly eight-year run of lying to physicians and the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies . . . .
>
> The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin.
> The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than

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[13] Letter from Andrew Hafter, FDA Div. of Drug Mktg., Advertising & Communications to Kenneth Palmer, Sanofi-Synthelabo Inc. (May 9, 2001), *available at* http://www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatory Information/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166467.pdf. *See also* Am. Ass'n for Justice, *Lawsuits question safety and efficacy of Plavix*, Trial, Mar. 1, 2007, *available at* http://www.thefreelibrary.com/Lawsuits +question+safety+and+efficacy+of+Plavix.-a0161024365 (M.W. Cert. Ex. E).

[14] *Compare*, M.W. Cert. Ex. B ¶¶ 25-27, *with* TAC ¶¶ 122-23. *See also* M.W. Cert. Ex. D.

[15] *See*, *e.g.*, Associated Press, *Study: Plavix raises risk for ulcers*, St. Petersburg Times, Jan. 20, 2005, *available at* http://www.sptimes.com/2005/01/20/Worldandnation/Study __Plavix_raises_.shtml (M.W. Cert. Ex. F); Jeff Evans, *Clinical Capsules: Preventing Recurrent Ulcer Bleeding*, Internal Medicine News, Mar. 1, 2005, *available at* http://www.internalmedicinenews.com/news/across-specialties/single-article/clinical-capsules/88286fa2b3fda368692e2abf0c8dab24.html (M.W. Cert. Ex. G).

> paying for a four-dollar ($4) a day Plavix pill that greatly increases the risk of stomach bleeding. M.W. Cert. Ex. B ¶¶ 25-27.

A summary of the public disclosures upon which Relator's TAC is based is attached to the Certification of M. Watson as Exhibit D.

Relator's TAC, at the very least, encompasses actions partly based on these public disclosures. *See Zizic*, 728 F.3d at 238 ("[T]he public disclosure bar covers actions simply 'based upon' public disclosures, including actions 'even partly based upon' such allegations or transactions"). At best, Relator's TAC adds only minor details that may be inferred from prior, broad public disclosures. For example, Relator alleges that P&T committees were targets of Defendants' alleged fraudulent promotion but adds only the most basic information that could be inferred by any observer, alleging only that "the persons that constitute these committees are the very same persons that BMS/Sanofi targeted with their false marketing – physicians and pharmacists." TAC ¶ 131. *See Zizic*, 728 F.3d at 238 (concluding that additional information was too insubstantial to prevent an otherwise substantially similar allegation from being based on public disclosure). Accordingly, the allegations in the TAC have been publicly disclosed.

B. Relator Is Not an Original Source of the Allegations

The TAC is thus based on publicly disclosed information and can proceed only if Relator demonstrates that she is the "original source" of the information upon which the allegations in the TAC are based, a showing that requires proof that Relator had "direct and independent" knowledge of the information on which the allegations are based. 31 U.S.C. § 3730(e)(4)(B) (2009); *Atkinson*, 473 F.3d at 520. Relator cannot demonstrate she is an original source of the FCA because she fails to plead how and when she obtained direct and independent knowledge of the alleged fraud. *See United States ex rel. Hafter v. Spectrum Emer. Care, Inc.*, 190 F.3d 1156, 1162 (10th Cir. 1999) ("[A] *qui tam* plaintiff must allege specific facts – as opposed to mere

conclusions – showing exactly how and when he or she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint and support those allegations with competent proof").[16]

Relator's broad allegations that she has direct and independent knowledge because of her position as a sales representative with Sanofi is insufficient. Nowhere does Relator allege that she has any direct or independent knowledge of any false statements made to any particular physician, of any given physician actually prescribing Plavix® instead of aspirin as a result of the alleged promotional scheme. *See id.* at 743; *Hafter*, 190 F.3d at 1162 (unsupported, conclusory allegations that relators had direct and independent knowledge were insufficient to establish jurisdiction).[17] Nor does, Relator allege that she ever had any contact at all with state

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[16] The FCA was amended as part of the Patient Protection and Affordable Care Act of 2010, Pub L. No. 111-148, 124 Stat. 119 (2010). The 2010 amendment modified the "original source" definition to include: "an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." *Id.* § 3730(e)(4)(B) (2010).

The result is the same under the post-2010 FCA because Relator has failed to allege sufficient facts to demonstrate that she had knowledge independent of the publicly disclosed allegations. Relator's allegations also fail to add materially to the prior public allegations because – after setting aside previous publicly disclosed information – Relator's TAC contains no facts that would be sufficient to form the basis of a claim under the FCA. *See United States ex rel. Osheroff v. Humana, Inc.*, No. 10-2448-cv, 2012 WL 4479072, at *12 (S.D. Fla. Sept. 28, 2012) (relator not an original source when non-publicly disclosed allegations were insufficient to support claims under the Anti-Kickback Statute, the Civil Monetary Penalties Law, or the FCA). *See also United States ex rel. Davis v. Dist. of Columbia*, 679 F.3d 832, 839 n.4 (D.C. Cir. 2012) (the 2010 amendment requires relator to provide information that "adds value" to publicly disclosed information).

[17] Relator cannot allege that she has any direct or independent knowledge as to any activities by BMS because she does not allege ever being employed at BMS, alleges no conduct by BMS or any of its employees, and does not allege that she even performed work related to Plavix® on behalf of BMS. *See* TAC, Ex. A ¶¶ 2-6; *United States. ex rel. Repko v. Guthrie Clinic P.C.*, No. 3:04cv1556, 2011 WL 3875987 (M.D. Pa. Sept. 1, 2011), *aff'd,* 490 F. App'x 502 (3d Cir. 2012)

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Medicaid P&T committees or representatives of Medicare Part D sponsor plans. *United States ex rel. Feldstein v. Organon, Inc.*, 364 F. App'x 738, 740-43 (3d Cir. 2010); *Zizic,* 728 F.3d at 237 (a relator who obtains information and additional facts from a third party lacks direct knowledge); *United States ex rel. Schumann v. Astrazeneca Pharm. LP*, Civ. Action No. 03-CV-5423, 2013 WL 300745, at *8 (E.D. Pa. Jan. 25, 2013) ("It is not enough, however, that the relator learn the information via his employment, but he must do so without deriving that information from others.").

Without pleading the particulars of how, when and from whom she learned of the supposed fraud, Relator fails to show she was an "original source." *See Stennett v. Premier Rehab. Hosp., LLC*, Civ. Action No. 08-782, 2011 WL 841074, at *1, 7 (W.D. La. Mar. 7, 2011), *aff'd*, 479 F. App'x 631(5th Cir. 2012) ("factual allegations fail[ed] to allege, with the specificity required by Rule 9(b) . . . that Plaintiff [wa]s the 'original source' of the information forming the basis of the complaint"); *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674-75 (8th Cir. 2003) (holding relator was not an original source because he did not adequately plead the circumstances of the alleged fraud under Rule 9(b)).

IV. THE SIX-YEAR STATUTE OF LIMITATIONS APPLICABLE TO THE FEDERAL AND MANY STATE FALSE CLAIMS ACTS BARS MANY OF RELATOR'S CLAIMS

Relator's federal FCA claims and many of their state law counterparts are subject to a six-year statute of limitations provision that bars Relator's claims to the extent they rely on

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(relator who left defendants' employ long before the events in question occurred did not have direct knowledge of the situation and was not an original source). Nor can she even assert she was an original source during the period she was not employed as a Plavix® sales representative at Sanofi. TAC, Ex. A ¶¶ 4-6 (Relator promoted Plavix® from 2003-2005 and 2008-2010). *See also Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475 (2007) (relator was not employed by defendant during period of relevant conduct); *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 352-53 (4th Cir. 2009) (relator was not employed by the defendant).

alleged conduct that occurred before March 30, 2005, six years before Relator filed her original complaint.[18] *See* 31 U.S.C. § 3731(b) (an FCA claim may not be brought "more than 6 years after the date on which the violation of section 3729 is committed"); *Atkinson*, 473 F.3d at 513-14 (noting the six-year statute of limitations under the FCA). Relator's allegations regarding Defendants' alleged false statements should therefore be limited to conduct occurring after March 30, 2005.[19]

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[18] All of the following statutes provide for a six-year limitations period that is substantively identical to that set forth in 31 U.S.C. § 3731(b)(1). *See* California False Claims Act, Cal. Gov't Code § 12654; Chicago False Claims Act, Municipal Code of Chicago § 1-22-040(b); Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-307(1); Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301*l*; Delaware False Claims and Reporting Act, Del. Code. tit. 6 § 1209(a)(1); District of Columbia Procurement Reform Amendment Act, D.C. Code 2-308.17(a); Florida False Claims Act, Fla. Stat. Ann. § 68.089(1); Georgia False Medicaid Claims Act, Ga. Code § 49-4-168.5; Hawaii False Claims Act, Haw. Rev. Stat. § 661-24; Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/5(b)(1); Indiana False Claims and Whistleblower Protection Act, Ind. Code. § 5-11-5.5-9(b)(1); Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5K; Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.614(1)(a); Minnesota False Claims Act, Minn. Stat. Ann. § 15C.11(a); Montana False Claims Act, Mont. Code Ann. § 17-8-404(1)(a); New Jersey False Claims Act, N.J. Stat. § 2A:32C-11a; Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.170(1); North Carolina False Claims Act, N.C. Gen. Stat. § 1-615(a); Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. § 63-5053.6(B)(1); Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-5(b)(1); Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-184(b); Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.9. Certain other states have longer or shorter statute of limitations periods and Relator's action should be limited accordingly. *See* New York False Claims Act, N.Y. State Fin. Law § 192(1) (10 years); Wisconsin Limitation of Actions for False Claims, Wis. Stat. Ann. § 893.981 (10 years); New Mexico Medicaid False Claims Act, N.M. Stat Ann. § 37-1-4 (4 years); *United States. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 818 (E.D. Tex. 2008) (holding Texas FCA claims are subject to a four-year statute of limitations under Tex. Civ. Prac. & Rem. Code § 16.051).

[19] *See* TAC ¶¶ 4-12, 115-117 (alleging false statements prior to March 30, 2005). *See also* TAC Exhibits F (summary of CAPRIE trial from 1996), G (CAPRIE Road Map), and I (Chan study dated January 20, 2005) which predate March 30, 2005.

V. THE COURT SHOULD DISMISS RELATOR'S REMAINING CLAIMS

Relator's allegations under the conspiracy provision of the federal FCA[20] and the false claims and Medicaid claims statutes of 26 different states or localities that are substantively similar to and/or track the language of the federal FCA must likewise be dismissed,[21] for all the reasons set forth above. Further, Relator's state law claims also fail for separate and independent reasons.

First, Relator failed to comply with the *qui tam* provisions of the state false claims acts because she fails to allege she provided all material evidence in support of her claims or served

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[20] Relator's conspiracy count must also be dismissed because she fails to allege an actionable false claim and does not identify any agreement between the Defendants to defraud the government for the purpose of receiving payment. *Bartlett*, 234 F.R.D. at124 (dismissing conspiracy count under the FCA because the complaint failed "to state the existence of an agreement to defraud the Government by the Defendants").

[21] Relator's action would be barred under state statutes which are identical or substantially similar to the pre-2010 public disclosure bar. *See* Cal. Gov't Code § 12652(d)(3)(A) (1999); Municipal Code of Chicago § 1-22-030(f); Colo. Rev. Stat. § 25.5-4-306(5)(c) (2010); Conn. Gen. Stat. § 17b-301i(a)(3) (2009); Del. Code. tit. 6 § 1206(c) (2009); D.C. Code § 2-308.15(c)(2)(a); Fla. Stat. Ann. § 68.087 (2003); Ga. Code § 49-4-168.2(j)(2) (2007); Haw. Rev. Stat. § 661-28 (2000); 740 Ill. Comp. Stat. Ann. 175/4(e)(4) (1996); Ind. Code. § 5-11-5.5-7(f); Mass. Gen. Laws ch. 12, § 5G(3) (2000); Mich. Comp. Laws § 400.610a(13); Minn. Stat. Ann. § 15C.05(c)(3) (2010); Mont. Code Ann. § 17-8-403(5)(c); Nev. Rev. Stat. Ann. § 357.100 (1999); N.J. Stat. § 2A:32C-9(c); N.M. Stat Ann. § 27-14-10(C); N.Y. State Fin. Law § 190(9)(b) (2007); N.C. Gen. Stat. § 1-611(d); Okla. Stat. Ann. § 63-5053.5(B); R.I. Gen. Laws § 9-1.1-4(e)(4) (2007); Tenn. Code Ann. § 71-5-183(e)(2)(A) (2005); Tex. Hum. Res. Code § 36.1113(b) (1997); Va. Code § 8.01-216.8 (2003). Relator's action would be barred under state-equivalents of the post-2010 public disclosure bar as well. *See* Cal. Gov't Code § 12652(d)(3)(A) (Jan. 1, 2013); Colo. Rev. Stat. § 25.5-4-306(5)(c) (Aug. 7, 2013); Conn. Gen. Stat. § 17b-301i(a)(3) (June 13, 2011); Del. Code. tit. 6 § 1206(c) (July 24, 2013); DC ST § 2-308.15(c)(2)(a) (Mar. 19, 2013); Fla. Stat. Ann. § 68.087 (July 1, 2013); Ga. Code § 49-4-168.2(k) (July 1, 2012); Haw. Rev. Stat. § 661-31 (July 9, 2012); 740 Ill. Comp. Stat. Ann. 175/4(e)(4) (Aug. 17, 2012); Mass. Gen. Laws ch. 12, § 5G(3) (July 1, 2013); Minn. Stat. Ann. § 15C.05(f) (Aug. 1, 2013); Mont. Code Ann. § 17-8-403(6) (July 1, 2013); Nev. Rev. Stat. Ann. § 357.100 (May 28, 2013); N.Y. State Fin. Law § 190(9)(b) (Aug. 27, 2010); R.I. Gen. Laws § 9-1.1-4(e)(4) (July 15, 2013); Tenn. Code Ann. § 71-5-183(e)(2)(A) (Apr. 11, 2013); Tex. Hum. Res. Code § 36.1113(b) (Sept. 1, 2011).

her complaint on any state other than Illinois as required by the law of the other co-plaintiff states and municipalities.[22]

Second, the California, Connecticut, District of Columbia, Delaware, Florida, Georgia, Indiana, Massachusetts, and North Carolina statutes authorize a relator to bring *qui tam* claims on behalf of the state only in the state's own courts. [23]

Third, the Court should dismiss nineteen of the state or municipality law counts to the extent that they are: (1) based on allegedly false claims submitted prior to the relevant state law's effective date where the statutes do not permit retroactive application,[24] and (2) where applying

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[22] *See United States ex rel. Fowler v. Caremark RX, Inc.*, No. 03-8714, 2006 WL 1519567, at *5 (N.D. Ill. May 30, 2006). (dismissal for "fail[ure] to comply with the *qui tam* provisions of the state false claims acts."); Cal. Gov't Code § 12652(c)(3); Municipal Code of Chicago § 1-22-030(b)(2); Colo. Rev. Stat. § 25.5-4-306(2)(b); Conn. Gen. Stat. § 17b-301d(b); Del. Code. tit. 6 § 1203(b)(2); D.C. Code 2-308.15(b)(2); Fla. Stat. Ann. § 68.083(3); Ga. Code § 49-4-168.2(c); Haw. Rev. Stat. § 661-25(b); Ind. Code. § 5-11-5.5-4(c); Mass. Gen. Laws ch. 12, § 5C(3); Mich. Comp. Laws § 400.610a(2); Minn. Stat. Ann. § 15C.05(e); Mont. Code Ann. § 17-8-406; Nev. Rev. Stat. Ann. § 357.080(5); N.J. Stat. § 2A:32C-5(d); N.M. Stat Ann. § 27-14-7(C); N.Y. State Fin. Law § 190 (2)(b); N.C. Gen. Stat. § 1-608(b)(2); Okla. Stat. Ann. § 63-5053.2(b)(2); R.I. Gen. Laws § 9-1.1-4(b)(2); Tenn. Code Ann. § 71-5-183(2); Tex. Hum. Res. Code § 36.102(a); Va. Code § 8.01-216.5(b); Wis. Stat. Ann. § 20.931(5)(b).

[23] *See* Cal. Gov't. Code §12652(c)(2); Conn. Gen. Stat. § 17b-301d(a); Del. Code. tit. 6 § 1201(c); D.C. Code Ann. § 2-308.15(b)(2); Fla. Stat. § 68.083(2)-(3); Ga. Code § 49-4-168.6 (2009); Ind. Code. § 5-11-5.5-4(a)(2); Mass. Gen. Laws ch. 12 § 5C(1)-(2); N.C. Gen. Stat. § 1-615 (e).

[24] Connecticut, *see* Conn. Gen. Stat. Ann. § 17b-301a *et seq.* (effective Oct. 5, 2009); Colorado § 25.5-4-303.5 (*qui tam* provision) (effective May 26, 2010); Delaware, *see* Del. Code Ann. tit. 6, § 1201 *et seq.* (effective June 30, 2000); Georgia, *see* Ga. Code § 49-4-168.1 *et seq.* (effective May 24, 2007); Hawaii, *see* Haw. Rev. Stat. § 661-21 *et seq.* (effective May 26, 2000); Indiana, *see* Ind. Code § 5-11-5.5-1 *et seq.* (effective July 1, 2005); Michigan, *see* Mich. Comp. Laws. Ann. § 400.610a(1) (*qui tam* provision) (effective January 3, 2006); Minnesota, *see* Minn. Stat. § 15C.01 *et seq.* (effective July 1, 2010); Montana, *see* Mont. Code Ann. § 17-8-401 *et seq.* (effective Oct. 1, 2005); New Jersey, *see* N.J. Stat. Ann. § 2A:32C-1 *et seq.* (effective Mar. 13, 2008); New Mexico, *see* N.M. Stat Ann. § 27-14-1 *et seq.* (effective Mar. 3, 2004); New York, *see* N.Y. State Fin. Law § 187 *et seq.* (effective Apr. 1, 2007); North Carolina, *see* N.C. Gen. Stat. § 1-605 *et seq.* (effective Jan. 1, 2010), Oklahoma, *see* Okla. Stat. Ann. § 63-5053.1 *et seq.* (effective Nov. 1, 2007); Rhode Island, *see* R.I. Gen. Laws § 9-1.1-1 *et seq.* (effective July 1, 2007);Virginia, *see* Va. Code Ann. § 8.01-216.1 *et seq.* (effective Jan. 1, 2003); City of Chicago, *see* Municipal Code of Chicago § 1-22-020 *et seq.* (effective Dec. 15, 2004).

laws retroactively would violate the *ex post facto* clause of the United States Constitution.[25]

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For the foregoing reasons, Relator's TAC should be dismissed with prejudice.

Dated: October 21, 2013

Respectfully submitted,

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[25] *See* Mass. Gen. Laws ch. 12, § 5A *et seq.* (enacted July 1, 2000); Mass. Gen. Laws ch. 12, § 5K(1); Wis. Stat. Ann. § 20.931 *et seq.* (effective Oct. 27, 2007); Wis. Stat. Ann. § 20.931(15); *See* U.S. Const. art. I, § 10, cl. 1; *see also Massachusetts v. Schering-Plough Corp.*, 779 F. Supp. 2d 224, 238 (D. Mass. 2011) (holding that retroactive application of the Massachusetts False Claims Act would violate the *ex post facto* clause because there was "clear proof" that the statute's sanctions were "so punitive either in purpose or effect as to transform the MFCA into a criminal penalty for *ex post facto* purposes" (internal quotation marks omitted)).